UNITED STATES DISTRICT COURT
EASTERN DISTRICT PENNSYLVANIA

VALUE DRUG COMPANY, et al., *Plaintiffs*, v. TAKEDA PHARMACEUTICALS U.S.A., INC., WATSON LABORATORIES, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., and AMNEAL PHARMACEUTICALS LLC, *Defendants*.	Civil Action No. 2:21-cv-03500-MAK

DEFENDANTS' PRETRIAL MEMORANDUM

Pursuant to the Court's March 14, 2023 Order, ECF No. 897, Defendants Takeda Pharmaceuticals U.S.A., Inc. ("Takeda"), Amneal Pharmaceuticals, LLC ("Amneal"), Watson Laboratories, Inc. ("Watson"), Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc. (together, "Teva"), and (collectively, "Defendants") respectfully submit this Pretrial Memorandum addressing the topics set forth in Local Rule of Civil Procedure 16.1 and Rule VI.A. of this Court's Policies and Procedures. Defendants reserve their rights to present further evidence and argument not summarized below.

I. FACTUAL SUMMARY

Plaintiffs are 19 wholesalers and distributors of pharmaceutical products who purchase from drug manufacturers and resell and distribute primarily to pharmacies.[1] Defendants are pharmaceutical manufacturers. Takeda manufactures and sells brand Colcrys, which is used to treat acute gout flares and Familial Mediterranean Fever ("FMF"). Amneal, Watson, and Teva are—or, in the case of Watson, were—generic drug manufacturers.[2]

Beginning in late 2011, Takeda filed patent infringement suits against Par, Amneal, and Watson (collectively, the "Generics") after each filed Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to sell generic Colcrys before the expiration of Takeda's patents.[3] In 2015, in the weeks leading up to a consolidated trial before Judge Robinson of the United States District Court for the District of Delaware, Takeda entered into separate settlement agreements with each Generic at different times. The settlements followed Court-ordered mediation discussions between Takeda and Par, Takeda and Amneal, and Takeda and Watson. Chief Magistrate Judge Thynge acted as mediator with respect to each separate mediation. With Magistrate Judge Thynge's involvement, each of the Generics independently negotiated its own respective settlement terms with Takeda, ultimately entering into separate settlement agreements with Takeda, each of which contained unique terms that were materially different than the others'. In each case, the settlements resolved uncertain and expensive patent litigation on terms that

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[1] Those 19 entities are: Value Drug Company, RDC Liquidating Trust by and through its trustee, Advisory Trust Group LLC, MLI Rx LLC, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, H.D. Smith, LLC, J.M. Blanco, Inc., Valley Wholesale Drug Co., LLC, Cardinal Health, Inc., Cardinal Health 110 LLC, Cardinal Health P.R. 120, Inc., McKesson Corporation, Morris & Dickson Co., L.L.C., Burlington Drug Company, Inc., Dakota Drug, Inc., Louisiana Wholesale Drug Company, Inc., North Carolina Mutual Wholesale Drug Company, Prescription Supply, Inc., and J M Smith Corporation d/b/a Smith Drug Company.

[2] In August 2016, Teva completed a merger and acquisition transaction where it acquired Watson, among other companies.

[3] The Court dismissed Par from the case with prejudice on September 20, 2022, after Par filed for bankruptcy. *See* ECF No. 521.

permitted the Generics to launch more than eight years before Takeda's last patent expires. Each settlement agreement was submitted to the U.S. Department of Justice ("DOJ") and U.S. Federal Trade Commission ("FTC") for review.

At trial, Plaintiffs will have the burden of proving by a preponderance of the evidence that these independent, different-in-time settlements together formed a single unlawful conspiracy to restrain trade (Count I—All Defendants), and/or that the alleged conduct allowed Takeda unlawfully to maintain monopoly power (Counts V-VI —Takeda Only). Plaintiffs cannot prove either of their claims, and Defendants will be entitled to a directed verdict.

A. The Colcrys ANDA Litigations

In December 2011, Par filed an ANDA seeking FDA approval to sell a generic Colcrys product prior to the expiration of Takeda's Colcrys patents. As the first generic manufacturer to file a complete ANDA with the FDA, Par became entitled to a 180-day exclusivity period that would preclude FDA from issuing final approval to any other ANDA until 180 days after Par first commercially marketed a generic Colcrys product. Watson and Amneal each filed ANDAs relating to Colcrys in July 2012 and September 2012, respectively. As part of their respective ANDA filings, each Generic certified that the Takeda Colcrys patents, which otherwise would have precluded the Generic from marketing a generic Colcrys product, were invalid or not infringed. Seeking to enforce its patents, Takeda filed lawsuits in the United States District Court for the District of Delaware against Par in August 2013, Amneal in October 2013, and Watson in September 2014 (collectively, the "Colcrys ANDA Cases") alleging infringement of 17 Takeda patents. The Colcrys ANDA Cases were consolidated before Judge Robinson and scheduled to be tried jointly in a bench trial beginning on December 9, 2015.

Leading up to trial, Takeda and the Generics agreed to narrow the claims set for trial to 24 patent claims covering seven of Takeda's Colcrys patents. If Takeda won its patent infringement

claims (at trial or on appeal to the Federal Circuit) as to any one of the 24 patent claims at issue, then the Generics would not be able to launch generic versions of Colcrys until the expiration of Takeda's patents in 2029.

B. Settlement of the Colcrys ANDA Litigations

Takeda settled its lawsuit against Par approximately two weeks before trial, with Amneal the day before trial, and with Watson on the morning trial was set to begin, while counsel for Takeda and Watson were in court prepared to deliver their opening statements. Each independent settlement negotiation and the resulting settlement terms are described below.

1. Takeda-Par Settlement

Settlement negotiations. On August 18, 2015, representatives of Par and Takeda attended a court-ordered mediation conference with Magistrate Judge Thynge. Following that mediation, Takeda and Par negotiated an agreement for Par to sell Takeda's Authorized Generic ("AG") "under generally the same commercial terms as in the Prasco agreement," (Takeda's then-current AG distributor).[4] After the general terms of Par's AG license were in place, in September 2015, Takeda and Par negotiated a January 1, 2024 licensed entry date on which Par could launch its own ANDA product. From September to November 2015, Par and Takeda exchanged draft term sheets and negotiated various provisions of the license agreement. On November 23, 2015, Takeda and Par executed Settlement, License, and Distribution and Supply Agreements (collectively, the "Par Settlement Agreement"), which were effective as of November 24, 2015.

Settlement terms. The Par Settlement Agreement contained licenses to sell both a Colcrys AG and Par's own ANDA Colcrys product. The AG license provided Par a royalty-bearing "non-exclusive license" to sell a Colcrys AG starting July 1, 2018, approximately 11 years before the

[4] An AG is an approved brand name drug that is marketed pursuant to the NDA but as a generic and without the brand name on its label.

last of Takeda's Colcrys patents expire. The Par ANDA product license provided a royalty-free licensed entry date for Par's ANDA product starting on January 1, 2024, approximately five years before the last of Takeda's Colcrys patents expire, with accelerated licensed entry permitted under certain conditions. Those acceleration conditions included that Par could begin selling its ANDA product as early as the date on which Takeda licenses the sale of any other ANDA product. On November 24, 2015, Takeda submitted the final executed Par Settlement Agreement to the FTC and DOJ and obtained a 45-day stay of the litigation from Judge Robinson to provide the agencies an opportunity to review the settlement. Neither agency objected.

2. Takeda-Amneal Settlement

Settlement negotiations. On August 19, 2015, Takeda and Amneal attended a Court-ordered mediation conference with Magistrate Judge Thynge serving as the mediator. During that mediation conference, and subsequently through early December 2015, Takeda and Amneal engaged in settlement negotiations closely supervised by Magistrate Judge Thynge. On November 12, 2015, Takeda sent a proposed term sheet offering Amneal an April 1, 2022 ANDA product entry date, and a one-time payment to Amneal in an amount to be determined that would represent Takeda's avoided litigation expenses by settling. The next day, on November 13, 2015, Takeda and Amneal had a call to discuss Takeda's proposal, and then, on November 16, 2015, Takeda sent another term sheet proposing an earlier licensed entry date of April 1, 2021. On November 20, 2015, Amneal counter-proposed an even earlier April 1, 2020 licensed entry date. During that period, the parties also engaged in frequent calls involving Magistrate Judge Thynge. For example, on November 30, 2015, there was a conference call with Judge Thynge to discuss potential settlement terms. On December 3, 2015, there was a call with Judge Thynge and outside counsel for Takeda and Amneal to further discuss a potential settlement. Two days later, December 5, 2015, there was another call with Judge Thynge. Judge Thynge also called and emailed Takeda's

outside counsel on December 7, 2015 with respect to potential settlement terms.

On December 8, 2015, Magistrate Judge Thynge made a "mediator's proposal" splitting the entry-date difference: an October 15, 2020 entry date, which she conveyed to outside counsel for both parties on a call that morning, and then had follow up calls with both Takeda and Amneal's in-house counsel early that afternoon. Following Takeda's agreement to that proposal, Amneal confirmed its agreement in an email sent at 4:11 PM EST on December 8, 2015, after which Takeda and Amneal circulated and executed a final term sheet reflecting the agreed-upon terms (the "Amneal Binding Term Sheet").

Outside counsel for Takeda and Amneal executed the Amneal Binding Term Sheet on the evening of December 8, 2015, and it was sent to Magistrate Judge Thynge for her signature that same night. Magistrate Judge Thynge approved the term sheet early the next morning and signed it that day. The Amneal Binding Term Sheet included an October 15, 2020 generic entry date (with accelerated licensed generic entry permitted under certain conditions, including upon the earliest day upon which Takeda licensed the sale of any other ANDA product) and a $3.65 million payment representing Takeda's avoided litigation expenses.

Settlement terms. The final Settlement and License Agreements between Takeda and Amneal (collectively, the "Amneal Settlement Agreement") were executed on March 11, 2016. Consistent with the Amneal Binding Term Sheet, the Amneal Settlement Agreement provided a royalty-free licensed entry date for Amneal's ANDA product on October 15, 2020 (approximately eight-and-a-half years prior to expiration of the last of Takeda's Colcrys patents at issue), with accelerated licensed generic entry permitted under certain conditions. Those acceleration conditions included that Amneal's licensed ANDA entry would be no later than the earliest date on which Takeda licensed the sale of any other ANDA product. The Amneal Settlement

Agreement also provided that Takeda would pay Amneal $3.65 million, "represent[ing] a portion of the estimated attorneys' fees and expenses avoided by Takeda by entering into this Settlement Agreement and License Agreement." The Amneal Settlement Agreement did not contain a Most Favored Nations clause ("MFN").[5] Takeda submitted both the Amneal Binding Term Sheet and final executed Amneal Settlement Agreement to the FTC and DOJ and obtained a 45-day stay of the litigation from Judge Robinson to provide the agencies an opportunity to review the settlement. Neither agency objected.

3. Takeda-Watson Settlement

Settlement negotiations. In June 2015, Watson made an initial settlement offer to Takeda that included a proposed February 17, 2028 licensed entry date for Watson's ANDA product—one year before the last expiration date of the patents covering Colcrys—with "standard acceleration triggers." These proposed acceleration triggers would accelerate Watson's license based upon (1) the date of a final court decision invalidating Takeda's patents; (2) the date any other generic was licensed by Takeda; (3) the date of any "at risk"[6] launch by another generic; (4) the date Takeda launched or licensed any AG other than the Prasco AG. In August 2015, Watson and Takeda discussed a potential settlement that would include those terms, as well as an MFN for Watson. Because the parties believed they were close to an agreement, the mediation conference that had been scheduled to take place on August 20, 2015 was canceled. The negotiations based on that initial framework reached an impasse in mid-November 2015. Subsequently, and in the lead-up to trial, Takeda and Watson re-initiated settlement discussions, which were overseen by

[5] An MFN is a contractual provision that entitles a contracting party (in this context, a generic manufacturer) the right to receive the most favorable terms that the counterparty (here, Takeda) grants to any other party, presently or in the future, regardless of whether the generic company itself negotiated for that benefit.

[6] An "at risk" launch is a decision to launch while Takeda's patents were still operative and without authorization from Takeda.

Magistrate Judge Thynge.

On the evening of December 8, 2015—the day before trial and after Takeda and Amneal had agreed to the terms of the Amneal Binding Term Sheet—Watson proposed to Takeda for the first time a new type of acceleration term whereby Takeda would license Watson to sell Watson's ANDA product for a certain time prior to the entry of any other generic manufacturer licensed to sell generic Colcrys by Takeda (other than Par and Amneal, who had already settled with Takeda upon terms that required Takeda to accelerate Par and Amneal's license to the earliest date Takeda licensed any other ANDA product). Late on December 8, 2015, Takeda proposed a 90-day acceleration period to Watson. Early in the morning of December 9, 2015 (the day trial was set to begin), Watson countered with a 180-day acceleration period. That same morning, hours before trial was scheduled to start, Takeda proposed to split the difference—a 135-day acceleration period—and Watson agreed. By that time on December 9, 2015, counsel for Takeda and Watson were in the courtroom, ready to present opening statements, so requested a short recess to permit Takeda and Watson's settlement negotiators to finalize their agreement. The Court agreed to that request and Takeda and Watson subsequently finalized and then executed a binding settlement term sheet (the "Watson Binding Term Sheet") on December 9, 2015.

Settlement terms. The Settlement and License Agreements between Takeda and Watson (collectively, the "Watson Settlement Agreement") were fully executed on January 7, 2016. Consistent with the Watson Binding Term Sheet, the Watson Settlement Agreement provided a royalty-free licensed entry date for Watson's ANDA product of October 15, 2020 (approximately eight-and-a-half years prior to expiration of Takeda's Colcrys patents), with accelerated licensed generic entry permitted under certain conditions. Those acceleration conditions included that, if Takeda licensed another ANDA product to launch before, or within 135 days after, October 15,

2020, then Watson's entry date would be accelerated to be 135 days before that ANDA product's entry date (the "135-Day Term"). As noted above, the 135-Day Term did not apply to Takeda's previously agreed upon licenses to Par and Amneal, as those licenses required that Par and Amneal's own ANDA products could launch as early as any other generic Colcrys product Takeda licensed. The Watson Settlement Agreement did not provide for any avoided litigation expense payment from Takeda to Watson, like that which Amneal had negotiated for itself. Takeda submitted both the Watson Binding Term Sheet and final executed Watson Settlement Agreement to the FTC and DOJ and obtained a 45-day stay of the litigation from Judge Robinson to provide the agencies an opportunity to review the settlement. Neither agency objected.

C. No Evidence of Coordination Among Takeda, Par, Amneal, and Watson

Discovery has not revealed any evidence of a conspiracy among Takeda, Par, Amneal, and Watson. Specifically, there is no evidence that:

- Any of the Generics (Par, Amneal, and Watson) ever disclosed any information about their settlement negotiations or settlement strategies with any other Generic;
- Amneal or Watson were involved in the negotiation of Par Settlement Agreement;
- Takeda or Par ever informed Amneal or Watson of the terms of the Par Settlement Agreement;
- Par knew, when it agreed to the Par Settlement Agreement, that Amneal and Watson would later settle or on what terms, including that they would agree to generic entry dates in October 2020;
- Par ever had knowledge of the terms of the Amneal or Watson Binding Term Sheets or Settlement Agreements, including that Watson and Takeda would later agree to the 135-Day Term;

- Par or Watson were involved in the negotiation of the Amneal Binding Term Sheet or Settlement Agreement;
- Takeda or Amneal ever informed Watson of the terms of the Amneal Binding Term Sheet or Settlement Agreement;
- Par or Amneal were involved in the negotiation of the Watson Binding Term Sheet or Settlement Agreement;
- Amneal, at the time Amneal agreed to the terms of the Amneal Binding Term Sheet, knew that Watson and Takeda would later agree to the 135-Day Term or that Watson would ask for and receive that type of provision at all; and
- Amneal ever had knowledge of the terms of the Watson Settlement Agreement, including the existence of the 135-Day Term.

D. The "Third Wave" Settlements

Plaintiffs allege that Takeda, Par, Amneal, and Watson each settled their respective litigations with a shared intent to hold off a "third-wave" of ANDA filers from entering the market (filers who, as of the time of each Generic's settlements, had not even filed ANDAs yet). In 2016, eight additional generic manufacturers filed ANDAs seeking to sell a generic Colcrys product. Seeking to enforce its Colcrys patents, Takeda sued each of them, and eventually settled with all of them in late 2017 and early 2018. Like Takeda's prior settlements with Par, Amneal, and Watson, these third-wave settlements were submitted to the DOJ and FTC for regulatory review. Neither agency objected. These settlements are not alleged to be a part of a conspiracy.

One third-wave generic, Mylan, launched its generic Colcrys product "at risk" in November 2019, based on its interpretation of an acceleration provision in its settlement agreement with Takeda. Other third-wave filers launched in 2020 pursuant to similar acceleration provisions

in their agreements. Amneal did not launch until May 2020—almost six months after Mylan, as the sixth generic on the market. Watson did not launch until December 2020—more than twelve months after Mylan, as the ninth generic. Par did not receive FDA approval for its ANDA product until August 2021 and still has not launched its ANDA product.

E. Plaintiffs Have No Evidence That Teva Would Have Been Able to Launch Its Generic Colcrys Product Earlier than January 2020

Plaintiffs allege that but-for the alleged conspiracy, Teva would have launched its generic Colcrys product by September 15, 2017. But the evidence shows that manufacturing safety considerations would have prevented Teva from launching its generic Colcrys product until January 2020, at the earliest.

Colchicine is an Occupational Hazard Category 5 ("OHC-5") substance. That means it is highly toxic and hazardous to operators exposed to it during manufacturing. Watson's ANDA for generic Colcrys stated that it would manufacture colchicine at its manufacturing facility in Goa, India. But Teva's environmental, health, and safety ("EHS") guidelines require the use of special, heavy-duty, built-in equipment, such as isolators and gloveboxes to manufacture OHC-5 products, and the Goa facility did not have that equipment.

After Teva acquired Watson on August 2, 2016—part of a multi-billion-dollar transaction that included dozens of Watson's manufacturing facilities and hundreds of drugs—Teva conducted a years-long, comprehensive review of the Watson facilities to ensure that they complied with Teva's EHS guidelines. By November 2017, Teva's EHS review of Goa was complete. Teva determined that it could not launch its Colcrys ANDA product from Goa because Goa was not equipped to manufacture OHC-5 products at that scale—Goa did not have isolators or other equipment needed to comply with Teva's EHS guidelines. Teva identified two options for the manufacture of generic Colcrys in a manner that complied with Teva's EHS guidelines: Teva

could transfer the manufacture of colchicine to another facility that was already OHC-5 compliant or Teva could invest in building out the necessary infrastructure at Goa to permit it to safely manufacture colchicine at the scale and volumes anticipated for generic Colcrys sales.

Teva evaluated both alternatives and concluded that its best option would be to transfer manufacturing of generic Colcrys to a facility located in Opava, the Czech Republic. Teva began that transfer process in January 2019. Transferring a manufacturing site and obtaining regulatory approval from the FDA for manufacture at the new site is a lengthy process. In this case, the transfer from Goa to Opava took nearly two years, causing Teva to be unable to launch generic Colcrys until December 2020.

In a hypothetical but-for world where Watson prevailed in the patent litigation, including any appeals, in 2017 as Plaintiffs allege, Teva still would have needed to manufacture generic Colcrys at a facility suitable for OHC-5 products under Teva's EHS guidelines. Teva, therefore, would have still needed to conduct the same EHS review it performed in the actual world, which—given the scope of that review of the dozens of newly acquired Watson facilities—Teva still would have completed in November 2017. However, Teva theoretically could have begun assessing options for the safe manufacture of generic Colcrys at that time, rather than beginning that assessment in July 2018, which is when that assessment began in the actual world. No other aspect of the site transfer from Goa to Opava could have proceeded on a faster timeline than it did in the actual world, which means that the earliest Teva would have been able to launch generic Colcrys in a but-for world where it had prevailed in the Colcrys patent litigation rather than settled for an October 2020 launch date would be January 2020, *after* Plaintiffs allege that the purported conspiracy had already come to an end as a result of Mylan's at-risk launch.

II. DEFENDANTS' DEFENSES

Defendants deny all of Plaintiffs' allegations. At trial, Plaintiffs will not be able to prove

any of their claims by a preponderance of the evidence. Because none of Plaintiffs' claims have merit, Defendants should not be liable for any damages.

Plaintiffs allege that all Defendants, together with non-party Par, entered into a single conspiracy in restraint of trade in violation of section one of the Sherman Act, 15 U.S.C. § 1. That claim fails for several reasons.

First, Plaintiffs cannot prove that each of Takeda, Par, Amneal, and Watson knowingly entered into a single conspiracy, with all three of the other entities, for the shared purpose of working together to restrict the supply of generic Colcrys, by each agreeing to a 135-day exclusivity period for the generic defendants. *Second*, Plaintiffs cannot prove that Takeda had market power in a properly-defined relevant antitrust market. *Third*, Plaintiffs cannot prove that the alleged conspiracy among Takeda, Par, Amneal, and Watson resulted in a substantial harm to competition in the relevant antitrust market. *Fourth*, Plaintiffs cannot prove that any anticompetitive effects of the alleged conspiracy among Takeda, Par, Amneal, and Watson substantially outweighed the procompetitive benefits of the challenged settlements. *Fifth*, Plaintiffs cannot prove that if Par, Amneal, and Watson had not entered the alleged conspiracy with Takeda, they would have gone to trial against Takeda in the Colcrys patent infringement case and won both (1) at trial in the United States District Court for the District of Delaware and (2) on any appeal to the United States Court of Appeals for the Federal Circuit, thereby invalidating Takeda's patents for Colcrys or proving that their generic Colcrys products did not infringe Takeda's patents. *Sixth*, Plaintiffs cannot prove that, but for the alleged conspiracy among Takeda, Par, Amneal, and Watson, both Amneal and Teva would have launched generic Colcrys by September 15, 2017, taking into account any manufacturing and/or regulatory obstacles that Teva and/or Amneal may have faced.

Plaintiffs also allege a claim under section two of the Sherman Act, 15 U.S.C. § 2, against Takeda. That claim also fails for a number of reasons.

First, Plaintiffs cannot prove that Takeda had monopoly power in a properly-defined relevant antitrust market. *Second*, Plaintiffs cannot prove that Takeda willfully acquired or maintained monopoly power in that market by engaging in anticompetitive conduct. *Third*, Plaintiffs cannot prove that they were injured because of Takeda's alleged anticompetitive conduct.

Finally, in all events, Plaintiffs cannot recover from any Defendant on any claim because Plaintiffs cannot prove that they are entitled to damages, because they cannot calculate the amount of overcharge damages that they are allegedly owed without guessing, speculating, or making unsupported assumptions and inferences. That is especially true because this case is not a class action, which means each individual Plaintiff must independently prove that it would have paid less for brand and generic Colcrys absent the alleged conspiracy, but the record lacks sufficient Plaintiff-specific evidence for each Plaintiff to make that showing.

III. RELIEF SOUGHT

Plaintiffs will not be able to meet their burden at trial. After the Plaintiffs have been fully heard on any of the issues they bear the burden of proving, Defendants will move for a directed verdict and ask the Court to enter a judgment in Defendants' favor on all counts that can only be maintained based on a favorable finding on that issue. If, at the conclusion of Plaintiffs' case, there remain any counts upon which Defendants have not already been granted judgment as a matter of law, Defendants will present their case for the jury to decide whether Plaintiffs have satisfied its burden of proof on any remaining issues and claims. If this case goes to the jury, Defendants respectfully submit that the Court should adopt Defendants' proposed jury instructions and proposed verdict form.

IV. DEFENDANTS' WITNESSES

Pursuant to Local Rule 16.1 and Rule VI.A.(3) of this Court's Policies and Procedures, Defendants hereby identify the names and addresses of all possible witnesses:

1. **Chris Alverson (Defendants May Call by Deposition)** (6535 N. State Highway 161 Irving, Texas 75039): Mr. Alverson is a Senior Vice President of Supply Chain Management at Plaintiff McKesson Corporation ("McKesson"). He is expected to testify about Plaintiff McKesson's business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury and damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

2. **Laurence C. Baker, Ph.D. (Takeda Will Call)** (Encima Commons, Room 118, 615 Crothers Way, Stanford, California 94305): Dr. Baker is one of Defendant Takeda's economists. He is expected to testify concerning the evidence put forward by Plaintiffs' economist, Dr. Russell L. Lamb, to support Plaintiffs' allegation that Defendants entered into a single conspiracy to "order the market" for generic Colcrys. Dr. Baker will also testify concerning Dr. Lamb's purported conclusions about the challenged settlement agreements' alleged economic effects on the market.

3. **Lawrence Brown (Defendants May Call)**[7] (1 Hartwell Place, Lexington, Massachusetts 02421): Mr. Brown was a Vice President of Intellectual Property at Par. He is expected to testify concerning Par's Colcrys ANDA litigation.

4. **Mark Buonaiuto (Defendants May Call by Deposition)** (631 White Oak Way, Yorkville, Illinois 60560): Mr. Buonaiuto was a Vice President and Chief Patent Counsel at Takeda. He is expected to testify concerning the Colcrys ANDA litigations.

5. **Mary Bourke (Takeda Will Call; Amneal and Teva/Watson May Call)** (Womble Bond Dickinson LLP, 1313 N. Market Street, Suite 1200, Wilmington, Delaware 19801): Ms. Bourke served as Takeda's outside counsel for the Colcrys ANDA litigations. She is expected to testify concerning the Colcrys ANDA litigations.

6. **J. Mark Bover (Defendants May Call)**[8] (195 Theater Drive, Duncansville, Pennsylvania 16635): Mr. Bover is the Vice President of Operations for Value Drug. He is expected to testify about Plaintiff Value Drug's business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury, and the allegations asserted in Plaintiffs' Second Amended Complaint.

7. **Carla Calabro (Defendants May Call)**: Ms. Calabro is the Senior Director of Pipeline & Business Analytics at Par. She is expected to testify regarding Par's

[7] Defendants reserve the right to call Mr. Brown by deposition if he does not appear live.

[8] Defendants reserve the right to call Mr. Bover by deposition if he does not appear live.

preparations for the launch of generic Colcrys.

8. **Paul Campanelli (Defendants May Call)** (Convey Health Solutions, 550 South Caldwell Street, Suite 900, Charlotte, North Carolina 28202): Mr. Campanelli was the President and Chief Executive Officer at Par. He is expected to testify concerning Par's settlement of the Colcrys ANDA litigation.

9. **Kenneth Cappel (Amneal Will Call; Takeda and Teva/Watson May Call)** (50 Back Brook Road, Ringoes, New Jersey 08051): Mr. Cappel was a Vice President of Global Intellectual Property at Amneal. He is expected to testify concerning Amneal's Colcrys ANDA litigation.

10. **Domenic Ciarico (Defendants May Call)**: Mr. Ciarico is the Chief Commercial Officer at Par. Mr. Ciarico is expected to testify concerning the litigation between Takeda and Mylan regarding Mylan's 2019 launch of generic Colcrys.

11. **Brian Coppola (Defendants May Call by Deposition)** (Southport, Connecticut, 06890): Mr. Coppola is the Managing Partner of Plaintiff MLI Rx LLC. He is expected to testify about Plaintiff MLI Rx's (and its corporate predecessor, Miami-Luken's) business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury and damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

12. **Pierre-Yves Cremieux, Ph.D. (Amneal and Teva/Watson Will Call)** (111 Huntington Avenue, Boston, Massachusetts 02199): Dr. Cremieux is Defendants' Amneal, Teva, and Watson's economist. He is expected to testify concerning the economic evidence put forward by Plaintiffs' economist, Dr. Russell L. Lamb, to support Plaintiffs' allegation that Defendants entered into a single conspiracy to "order the market" for generic Colcrys.

13. **Nicholas Davies (Teva/Watson Will Call)** (4242 Six Forks Road, Raleigh, North Carolina 27609): Mr. Davies is Teva's supply chain and manufacturing expert. He is expected to respond to the opinions offered by Plaintiffs' experts Donald S. Allen and Bernice Tao, particularly as they relate to Teva's preparations, and but-for timelines, for the U.S. launch of a generic version of Colcrys.

14. **Matthew Davis, M.D., RPh (Defendants May Call)** (1510 N. Valley Road, Malvern, Pennsylvania 19355): Dr. Davis was the Chief Medical Officer for URL Pharma, Inc. He is expected to testify concerning the development and invention of Takeda's Colcrys product.

15. **Francis DiGiovanni (Defendants May Call)**: Mr. DiGiovanni served as Takeda's outside counsel in the litigation between Takeda and Mylan regarding Mylan's 2019 launch of generic Colcrys. He is expected to testify concerning that litigation.

16. **Paul Doghramji, M.D., F.A.A.F.P. (Takeda May Call)** (555 Second Avenue, Collegeville, Pennsylvania 19426): Dr. Doghramji is Takeda's expert physician. He is expected to testify concerning the technical issues underlying infringement

and validity of certain of Takeda's Colcrys patents.

17. **Ken Einhorn (Defendants May Call by Deposition)** (816 Ellis Road, Durham, North Carolina 27703): Mr. Einhorn is the Executive Vice President of Purchasing at Plaintiff North Carolina Mutual Wholesale Drug Company, Inc. ("Mutual Drug"). He is expected to testify about Plaintiff Mutual Drug's business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury and damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

18. **Porter Fleming (Defendants May Call)**: Mr. Fleming served as Takeda's outside counsel in the litigation between Takeda and Mylan regarding Mylan's 2019 launch of generic Colcrys. He is expected to testify concerning that litigation.

19. **William Gazda (Takeda Will Call; Amneal and Teva/Watson May Call)** (95 E. Hayden Avenue, Lexington, Massachusetts 02421): Mr. Gazda is the Head of Established Brand Portfolios for Takeda. He is expected to testify concerning the commercialization, sale, and pricing of branded and authorized generic versions of Colcrys, as well as to general background on Takeda and its Colcrys product.

20. **Chad Gielen (Defendants May Call by Deposition)** (2085 I-49 S. Service Road, Sunset, Louisiana 70584): Mr. Gielen is the President and Chief Executive Officer of Plaintiff Louisiana Wholesale Drug Company, Inc. ("LWD"). He is expected to testify about Plaintiff LWD's business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury and damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

21. **Carrie Groff (Teva/Watson Will Call; Takeda and Amneal May Call)** (2009 Willow Oak Lane, Cedar Knolls, New Jersey 07927): Ms. Groff is the Director of New Product Introduction at Teva. Ms. Groff is expected to testify regarding the manufacturing, launch, and commercialization of Teva's generic Colcrys product.

22. **Kapil Gupta (Amneal Will Call; Takeda and Teva/Watson May Call)** (47 Bellwood Avenue, South Setauket, New York 11720): Mr. Gupta leads Business Development and Portfolio Strategy at Amneal. Mr. Gupta is expected to testify regarding Amneal's preparations for the launch of generic Colcrys**.**

23. **Kevin Hawkey (Defendants May Call by Deposition)** (410 Kay Lane Shreveport, Louisiana 71115): Mr. Hawkey is the Head of Purchasing at Plaintiff Morris & Dickson Co., L.L.C. ("Morris & Dickson"). He is expected to testify about Plaintiff Morris & Dickson's business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury and damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

24. **Martin Igel (Defendants May Call by Deposition)** (7000 Cardinal Place, Dublin, Ohio 43017): Mr. Igel is the Vice President of Global Sourcing at Plaintiff Cardinal Health, Inc ("Cardinal Inc."). He is expected to testify about Plaintiff Cardinal Inc.'s (and its corporate affiliates' Plaintiffs Cardinal Health 110 LLC's and

Cardinal Health P.R. 120, Inc.'s) business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

25. **Anupam B. Jena, M.D., Ph.D. (Defendants Will Call)** (180 Longwood Avenue, Boston, Massachusetts 02115): Dr. Jena is one of Defendants' economists. He is expected to testify concerning Dr. Lamb's opinion that the relevant antitrust market is limited to branded and generic Colcrys and that Takeda possessed market power in that purported market.

26. **Karen Keller (Defendants May Call)** (Shaw Keller LLP, 1000 N West St., Wilmington, DE 19801): Ms. Keller served as Par's outside counsel in the litigation between Takeda and Mylan regarding Mylan's 2019 launch of generic Colcrys. She is expected to testify concerning that litigation.

27. **Matthew Kipp (Defendants May Call by Deposition)** (1101 Lund Boulevard, Anoka, Minnesota 55303): Mr. Kipp is the General Counsel of Plaintiff Dakota Drug Inc. ("Dakota Drug"). He is expected to testify about Plaintiff Dakota Drug's business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury and damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

28. **George Kokkines (Defendants May Call by Deposition)** (52 E. Warson Court, Vernon Hills, Illinois 60061): Mr. Kokkines was an Associate General Counsel of Litigation and Compliance at Takeda. He is expected to testify concerning the Colcrys ANDA litigations.

29. **Scott M. Lassman (Defendants Will Call)** (1717 K Street, N.W., Suite 900, Washington, D.C. 20006): Mr. Lassman is Defendants' expert on FDA law. He is expected to testify concerning the potential forfeiture of Par's regulatory exclusivity period and related FDA regulatory issues.

30. **Heather Odenwelder (Defendants May Call by Deposition)** (1 West First Avenue, Conshohocken, Pennsylvania 19428): Ms. Odenwelder is a Vice President of Global Generic Sourcing at Plaintiff AmerisourceBergen Corporation ("ABC"). She is expected to testify about Plaintiff ABC's (and its corporate affiliates' AmerisourceBergen Drug Corporation's, H.D. Smith, LLC's, J.M. Blanco, Inc.'s, and Valley Wholesale Drug Co., LLC's) business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury and damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

31. **Dominic Pagnotta (Defendants May Call by Deposition)** (54 Creek Point Road, Ocracoke, North Carolina 27960): Mr. Pagnotta was the Chief Information Officer at Rochester Drug Cooperative, Inc., which is now known as Plaintiff RDC Liquidating Trust by and through its trustee, Advisory Trust Group LLC ("RDC"). He is expected to testify about Plaintiff RDC's business operations, purchasing

decisions with respect to branded and generic Colcrys, alleged injury and damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

32. **Thomas Schoen (Defendants May Call by Deposition)** (2233 Tracy Road, Northwood, Ohio 43619): Mr. Schoen is the President of Plaintiff Prescription Supply, Inc ("Prescription Supply"). He is expected to testify about Plaintiff Prescription Supply's business operations, purchasing decisions with respect to branded and generic Colcrys, alleged injury and damages, and the allegations asserted in Plaintiffs' Second Amended Complaint.

33. **Jonathan Singer (Takeda Will Call)** (Fish & Richardson P.C., 12860 El Camino Real, Suite 400, San Diego, California 92130): Mr. Singer is one of Takeda's patent experts. He is expected to testify concerning Takeda's likelihood of prevailing in the ANDA litigations and the opinions offered by Plaintiffs' experts Glen Belvis and Peter Gorevic.

34. **Victoria Spataro (Teva/Watson Will Call; Takeda and Amneal May Call)** (14 Saddle Road, Far Hills, NJ 07931): Ms. Spataro was Counsel of Intellectual Property at Watson. She is expected to testify concerning Watson's Colcrys ANDA litigation.

35. **Bruce Strombom, Ph.D. (Defendants Will Call)** (333 S. Hope Street, Suite 2700, Los Angeles, California 90071): Dr. Strombom is one of Defendants' economists. He is expected to testify concerning Dr. Lamb's opinions on antitrust impact and damages.

36. **Lars Taavola (Amneal Will Call; Takeda and Teva/Watson May Call)** (53 Frontage Road, Hampton, New Jersey 08827): Mr. Taavola was Senior Patent Counsel – Head of Patent Litigation at Amneal. He is expected to testify concerning Amneal's settlement of the Colcrys ANDA litigation.

37. **Heather Takahashi (Defendants May Call by Deposition)** (Munger, Tolles & Olson LLP, 350 South Grand Avenue, Los Angeles, California 90071): Ms. Takahashi served as Takeda's outside counsel for the Colcrys ANDA litigations. She is expected to testify concerning the Colcrys ANDA litigations.

38. **Hon. Mary Pat Thynge, U.S.M.J. (Ret.) (Takeda Will Call; Amneal and Teva/Watson May Call)** (Wilmington, Delaware): Judge Thynge was the magistrate judge assigned to the Colcrys ANDA litigations. She is expected to testify concerning her involvement in the settlements of those coordinated litigations.

39. **R. Polk Wagner (Amneal and Teva/Watson Will Call)** (3501 Sansom Street, Philadelphia, Pennsylvania 19104): Mr. Wagner is Defendants Amneal's and Teva/Watson's patent expert. He is expected to testify concerning the opinions offered by Plaintiffs' patent expert, Glen Belvis, concerning the Colcrys patent litigation and infringement and validity of Takeda's Colcrys patents at issue in the litigation.

40. **Jeffrey Weinberger (Takeda Will Call; Amneal and Teva/Watson May Call)** (350 S Grand Ave, Los Angeles, California 90071): Mr. Weinberger served as Takeda's outside counsel for the Colcrys ANDA litigations. He is expected to testify concerning the Colcrys ANDA litigations.

Defendants reserve the right to amend and supplement this list based on rulings by the Court and proceedings at trial and to question or call to testify any witness identified by any Plaintiff.

B. Defendants' Deposition Designations

Pursuant to Rule VI.A.(2) of this Court's Policies and Procedures, "highlighted deposition testimony (including videotaped deposition testimony) of admissions or unavailable witnesses which [Defendants] intend[] to offer during [their] case-in-chief," as well as "citations to the page and line number," is attached as Exhibit 1.

V. EXHIBITS

Pursuant to Local Rule 16.1 and Rule VI.A.(4) of this Court's Policies and Procedures, Defendants' schedules of exhibits to be offered at trial are attached hereto as Exhibit 2.

VI. ISSUES AND STIPULATIONS

Defendants respectfully request that the Court approve the following trial procedures that are either departures from the Trial Procedure set forth in Section X of the Court's Policies and Procedures, or address issues of trial procedure with respect to which the Court's Policies and Procedures are silent.

A. Attorneys Permitted to Examine Witnesses and Present Argument

In light of the complexity of the case and the fact that there are unique arguments and defenses applicable to individual Defendants, Defendants request that Rule X.J of the Court's Policies and Procedures be modified to permit each of Takeda, Amneal, and Teva/Watson to have counsel examine witnesses and to permit each of Takeda, Amneal, and Teva/Watson respectively

to have their counsel address the jury during opening and closing statements.

Good cause exists for modification of the "one attorney for each side" limitation set forth in Rule X.J of the Court's Policies and Procedures. Each Defendant must address claims, issues, and defenses that are unique to them. For example, Takeda alone is alleged to have engaged in monopolization, and Takeda's defenses to Plaintiffs' Counts V and VI are unique to Takeda. Teva/Watson have a unique causation defense related to the fact that Teva's EHS policies would have prevented Teva from launching its generic Colcrys product until at least January 2020, if not later, even under a scenario where patent or regulatory barriers to Teva's launch had not existed. And Amneal has defenses related to the fact that none of the settlement terms Plaintiffs allege had an anticompetitive effect exist in Amneal's term sheet or settlement agreement and, specifically, there is no evidence the 135-Day Term was ever known to Amneal. In order to allow each Defendant to present its defenses fully and adequately to the jury, each of Takeda, Amneal, and Teva/Watson should be permitted to have its counsel address the jury through unique opening and closing statements.

For similar reasons, as well as the fact that Takeda, on the one hand, and Amneal and Teva/Watson, on the other hand, have non-overlapping interests and are represented by separate counsel, each of Takeda, on the one hand, and Amneal and Teva/Watson, on the other hand, should be permitted to have their respective counsel examine witnesses. As they have throughout this case, Defendants' counsel will endeavor to cooperate and will seek to limit the instances where there is a need for defense counsel to separately examine a witness. However, to the extent a need arises, Defendants respectfully request that their ability to present their own defenses should not be limited by decisions made by counsel who do not represent them.[9]

[9] Defendants further request that, in the interest of efficiency, it be the case that any objection to trial questioning or evidence lodged by counsel for any Defendant at trial stand as an objection by all Defendants. This

B. Placeholder "Custodian of Records" Witnesses

Plaintiffs have served trial subpoenas on an unidentified "custodian of records" for each of Amneal, Teva, and Watson. As counsel for Amneal, Teva, and Watson and explained in their July 27, 2023 correspondence to Plaintiffs (attached as Exhibit 3), Plaintiffs' trial subpoenas to placeholder corporate witnesses fail to comply with Rule 45, which requires that the subpoena identify a specific individual, not a corporation. *See Bd. of Regents Univ. of Texas Sys. v. Bos. Sci. Corp.*, 2023 WL 346243, at *2 (D. Del. Jan. 20, 2023) ("the Court finds that the plain text of Rule 45 prohibits directing a subpoena to attend trial to a corporation"). Furthermore, Plaintiffs have informed Defendants that they intend to include on their trial witness list unidentified "custodians of record" for Amneal and Watson. Plaintiffs' placeholder categories fail to identify "the name and . . . address and telephone number of each witness" to be called at trial, as Rule 26(a)(3) requires. Amneal and Watson respectively request that the Court strike these placeholder witness categories.

C. Opening Statements and Summations

Defendants refer the Court to the separate statement submitted pursuant to the Court's August 9, 2023 Order (ECF No. 983).

D. Trial Time Allocation and Equal Division of Trial Time

Defendants refer the Court to the separate statement submitted pursuant to the Court's August 9, 2023 Order (ECF No. 983).

E. Order Regarding E-mail Time Stamps

Defendants proposed a stipulation regarding certain e-mail time stamps, but Plaintiffs refused to engage. The e-mail documents in this case were not sent from the same time zone. That

rule will further minimize the prospect of any disruptions to trial, while maintaining Defendants' respective ability to raise or preserve evidentiary issues.

created some witness confusion during depositions and will likely be a source of jury confusion at trial. In order to address that issue, Defendants proposed a stipulation that would create a process for the parties to add timestamps in Eastern Standard Time to e-mails sent or received between December 7, 2015 and December 10, 2015 in order to avoid any confusion at trial about the timeline of events. Defendants ask the Court to permit that process. Doing so would greatly reduce the risk of juror confusion (*e.g.*, thinking an e-mail sent from the West Coast was actually sent earlier than an e-mail sent from the East Coast, when the opposite is true) and would not be burdensome on the parties since it would only apply to approximately 57 exhibits (65 total, 8 of which are duplicates across the parties' proposed exhibit lists).

VII. STIPULATIONS OF COUNSEL

Pursuant to Rule VI.A.(1) of this Court's Policies and Procedures, there are no stipulations of counsel at this time.

Dated: August 15, 2023

Respectfully submitted,

KIRKLAND & ELLIS LLP
/s/ Karl Gunderson

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CERTIFICATE OF SERVICE

I, Karl Gunderson, hereby certify that on August 15, 2023, I served the foregoing document by electronically filing it with the Clerk of Court using the CM/ECF System, which will send an electronic notice to the registered participants as identified in the Notice of Electronic Filing.

/s/ Karl Gunderson
Karl Gunderson